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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,415	03/12/2004	Rebecca Guggemos Bakker-Arkema	A0000343-B	7133
28880	7590	01/19/2005	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,415

Applicant(s)

BAKKER-ARKEMA ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 7, 9, 10, 12, 13 and 15 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 11 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 3-15 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed November 29, 2004 has been received and entered into the application. Accordingly, claims 1-2 have been canceled and the specification at page 1 as well as claims 3-15 have been amended.

In light of the above amendments, the objection to the specification and rejections of claims 7-8 under 35 U.S.C. § 112, first and second paragraph and of claims 1, 2, 5, 7, 9, 10, 12, 13 and 15 under 35 U.S.C. § 102(e), as set forth in the previous Office action dated August 30, 2004 are withdrawn.

Claim Objections

Claims 11 and 14 are objected to because the term "further" in the expression "further comprises" is incorrect. The term "further" is not appropriate because conivaptan and/furosemide are not additional active agents, but rather species of the vasopressin antagonist and diuretic, respectively, that are already specified as being present in claim 3. The term "further" should be deleted.

Claims 6, 8, 11 and 14 are objected to as depending from a rejected base claim (see below), but are otherwise in condition for allowance.

Claim Rejection - 35 USC § 103

Claims 3-5, 7, 9, 10, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis-Grosse et al. (U.S. Patent No. 6,420,358) in view of Tanaka et al. (U.S. Patent No. 5,723,606), each of record, for the reasons of record as set forth in the previous Office action dated August 30, 2004, as applied to claims 1-15.

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Applicants' arguments at pages 7-9 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicants have argued that the presently claimed subject matter would not have been obvious because results have been demonstrated for the combination of conivaptan and furosemide, i.e., present specification at page Table 1 and Figures 1-3, that would not have been expected by one of ordinary skill in the art from the references relied upon by the Examiner.

The Examiner will agree that the results demonstrated in the present specification for the combination of conivaptan and furosemide would not have been expected by one of ordinary skill in the art. Therefore, claims directed to this combination are no longer subject to the present rejection, i.e., claims 6, 8, 11 and 14. The claims subject to the present rejection remain properly rejected, however, because they are not commensurate in scope with the showing of unobviousness with respect to the vasopressin antagonist and diuretic.

The Showing of Unobviousness is Not Commensurate in Scope with the Claims

As noted above, the Examiner acknowledges that unexpected results have been demonstrated in the present specification. These results, however, do not provide a basis for concluding that the claimed subject matter would not have been obvious because the results are limited to only a single vasopressin antagonist, i.e., conivaptan, and a single diuretic, i.e., furosemide, while the claims subject to this rejection encompass all of the vasopressin antagonists represented by the general structure I in claim 3 and all diuretics. Further, it has not been argued or demonstrated on the record that the results obtained with conivaptan and

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furosemide would be exemplary of results that would occur with all possible combinations of vasopressin antagonists and diuretics that are encompassed by the claims.

In this regard, the Examiner cites MPEP 2144.08(II)(B) which reads in-part:

“When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a prima facie case of obviousness. *Id.* For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a prima facie case of obviousness if a skilled artisan 'could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof.' *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see, *In re Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with 'an alkali metal' where it was well known in the catalyst art that different alkali metals were not interchangeable and applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506,

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508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way)." (emphasis added).

Here, a single vasopressin antagonist/diuretic combination has been tested and shown to possess unexpected properties. However, just as a single point in space fails to define a line, the results demonstrated for this one particular combination are not deemed sufficient to establish non-obviousness of all of the presently claimed vasopressin antagonist/diuretic combinations.

For the above reasons, the claims are deemed properly rejected.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J. Henley III
Primary Examiner
Art Unit 1614

January 15, 2005